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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/827,172	04/19/2004	James Dobbie	2785-1-002	2418

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KLAUBER & JACKSON
411 HACKENSACK AVENUE
HACKENSACK, NJ 07601

EXAMINER	
KISHORE, GOLLAMUDI S	

ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/827,172	DOBBIE, JAMES	
	Examiner	Art Unit	
	Gollamudi S. Kishore, Ph.D	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 May 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *16-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment dated 5-20-08 is acknowledged.

Claims included in the prosecution are 1-15.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The meets and bounds of 'lamellar bodies' and 'linear macromolecules' in claims 1 and 7 are unclear.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that these terms are expressly defined in paragraphs 0022 and 0033 of the specification. These arguments are not persuasive. 0022 and 0033 state the following.

> [0022] "Lamellar bodies or microbodies "as used throughout this document, refers to
> phospholipid, multilamellar, bilayered structures present in many tissues throughout the body,
> but also refers to the synthetic multilayered phospholipid structures having the novel
> composition described in the present invention. Thus, this term refers to both naturally
> occurring and synthetic lamellar bodies.
>
> [0033] Throughout this document the term "linear macromolecule" refers to molecules
> which are linear at the molecular level and whose structure essentially comprises the multiple
> repetition in linear sequence of units derived from molecules of low relative

> molecular mass.
> The molecules may possess side-chains, but these will not typically participate in chemical
> cross-linking. Examples of linear macromolecules of this species include mucus, DNA, actin
> and alginate.

Instant claims are composition claims and how can the structures present in many tissues throughout the body be used in the composition? How are they isolated to modify the linear macromolecules? The examiner is unaware of any multilamellar structures present in the body tissues and applicant has not shown any evidence. In essence, 'lamellar bodies' is not defined in clear terms. With regard to 'linear macromolecule', the definition includes the terms such as 'may possess' and 'include'. This is not a specific term for the term. The rejection is maintained.

Claim Rejections - 35 USC § 102

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-15 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 01/72277 of record.

WO teaches liposome compositions containing phosphatidylcholine, sphingomyelin, phosphatidylethanolamine, phosphatidylserine, phosphatidyl inositol and cholesterol in claimed amounts (pages 5, 6, 15-17 and claims, 7 and 9 in particular). The intended use has no significance in the composition claims.

4. Claims 1, 6, 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Schmitz (Journal of Lipid Research, 1991) of record or Post (Experimental Lung

Research, 1982) or Nemechek (1997) of record or King et al (Am J Physiol Lung Cell Mol physiol. 2002).

Schmitz teaches lung surfactant compositions containing lamellar bodies (Abstract and Table 2). Similarly Post, and King disclose lamellar bodies containing instant components (Tables 3 and 4 of Post; L289, the paragraph bridging columns 1 and 2 of King).

Nemechek teaches the use of nebulized bovine lung surfactant for experimentally induced Otitis media (page 476, col. 2).

Applicant's arguments to the above rejections and the declarations submitted to the above rejections have been fully considered, but are not persuasive. Applicant argues that the inventive aspect of the invention relates to the recognition that the composition is effective in modifying linear macromolecules, which are gel forming such as mucin and that in turn this indicates potential therapeutic uses in a wide range of disease states such as cystic fibrosis and otitis media. Applicant further argues that the prior art does not teach or suggest that the specific composition of the present invention would demonstrate significant effect on linear macromolecules as recited in claims 1 and 7 and by way of dependency the remaining claims. According to applicant, Nemecheck teaches that bovine ling surfactant does not necessarily correlate with the specific composition being claimed and would not lead one of ordinary skill in the art to believe that lamellar bodies can modify linear biological molecules and the prior art does not teach the amounts of phospholipid mixtures necessary to obtain the structures as

recited in the instant claims. These arguments are not persuasive since instant claims are composition claims and intended use has not significance in composition claims.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-4, 6-10 and 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over King et al (Am J Physiol Lung Cell Mol physiol. 2002).

King discloses a composition containing lamellar bodies. The composition contains phosphatidylcholine, PG, PS, PI, sphingomyelin and cholesterol. King discloses the amounts of these components in molar ratios (L289, the paragraph bridging columns 1 and 2) and not weight ratios. King also discloses the PC, PG, PI, sphingomyelin and PS in natural lung surfactants on col. 1, first paragraph on the same page. Assuming that the amounts of the components in the synthetic lamellar bodies of King are different weight percentages, since the purpose of King is to study the viscosities of various synthetic surfactant compositions resembling natural lung surfactants, it would have been obvious to vary the amounts to obtain the best possible combination resembling the natural surfactant. It should be pointed out that the sphingomyelin amount in natural surfactants taught by King is only 2 %

7. Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nemechek (1997) by itself in combination with WO 01/72277 or Nemechek, in combination with King cited above and WO 01/72277.

Nemechek teaches the use of nebulized bovine lung surfactant for experimentally induced Otitis media (page 476, col. 2). Although Nemechek does not teach the amounts of PC, PI, PS, PG, sphingomyelin and cholesterol specifically, the reference of King teaches bovine lung surfactant contains approximately the same claimed amounts except for sphingomyelin, which is only 2 % (see paragraph 1, col. 1, L278).

The teachings of WO have been discussed above. WO further teaches That sphingomyelin provides flexibility and softness to lamellar bodies (page 16, lines 30-34). The amounts of sphingomyelin taught are 19 % (claim 7).

To increase the percentage of sphingomyelin in Nemechek would have been obvious to one of ordinary skill in the art since sphingomyelin provides softness and flexibility to lamellar bodies as taught by WO.

Applicant's arguments to the 103 rejections have been fully considered, but are not persuasive. Applicant once again argues that the inventive aspect of the invention relates to the recognition that the composition is effective in modifying linear macromolecules, which are gel forming such as mucin and that in turn this indicates potential therapeutic uses in a wide range of disease states such as cystic fibrosis and otitis media. Applicant further argues that the prior art does not teach or suggest that the specific composition of the present invention would demonstrate significant effect on

linear macromolecules as recited in claims 1 and 7 and by way of dependency the remaining claims. According to applicant, Nemecheck teaches that bovine ling surfactant does not necessarily correlate with the specific composition being claimed and would not lead one of ordinary skill in the art to believe that lamellar bodies can modify linear biological molecules and the prior art does not teach the amounts of phospholipid mixtures necessary to obtain the structures as recited in the instant claims. These arguments have been fully considered, but are not persuasive since as pointed out above, instant claims are compositions claims and the motivation to modify need not be the same as applicant's. Furthermore, applicant has not shown that the composition of Nemechek does not modify the lung surfactant protein which is a linear molecule. Applicant's arguments based on the declarations are not persuasive. First of all, it is unclear as to what LMS-661 is and what it contains. Secondly, the scope of the claims is broad in terms of 'lamellar bodies' which according to applicant's own definition includes even bodies which are present in tissues and occur naturally. Third, comparison of this LMS-661 is made with L4031 and L4395 and not with the prior art compositions used in the rejections.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.

1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1-15 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 8, 11-13 and 15 of copending Application No. 10/678,743. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims in both applications recite the same lamellar body compositions with overlapping percentages for individual components and therefore, instant claims are anticipated by the claims in the copending application. Instant claim 1 is generic with respect to the individual components and it would have been obvious to one of ordinary skill in the art to vary the components in the lamellar bodies (liposomes) with a reasonable expectation of success since the use of the liposomes depends upon the disease to be treated.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant indicates willingness to consider filing a terminal disclaimer. The rejection is maintained in abeyance.

10. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Krass Frederick can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gollamudi S Kishore, Ph.D/
Primary Examiner, Art Unit 1612

GSK